



**BILLING CODE 6560-50-P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA-HQ-OPP-2011-0507; FRL-9340-9]**

**RIN 2070-ZA16**

**Dicloran and Formetanate; Proposed Tolerance Actions**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to revoke certain tolerances for the fungicide dicloran and the insecticide formetanate hydrochloride because, in follow-up to voluntary requests from registrants, domestic registrations were voluntarily amended to delete specific uses, leaving no dicloran and formetanate hydrochloride registrations for those uses. Also, in accordance with current Agency practice, EPA is proposing to make minor revisions to the tolerance expressions for dicloran and formetanate hydrochloride and to specific tolerance nomenclatures for dicloran.

**DATES:** Comments must be received on or before *[insert date 60 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2011-0507, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

*Instructions:* Direct your comments to docket ID number EPA-HQ-OPP-2011-0507. EPA's policy is that all comments received will be included in the docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or email. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your

comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

*Docket:* All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Joseph Nevola, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460-0001; telephone number: (703) 308-8037; email address: [nevola.joseph@epa.gov](mailto:nevola.joseph@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit II.A. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:
- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
  - ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
  - iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
  - iv. Describe any assumptions and provide any technical information and/or data that you used.
  - v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
  - vi. Provide specific examples to illustrate your concerns and suggest alternatives.
  - vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
  - viii. Make sure to submit your comments by the comment period deadline identified.

*C. What Can I do if I Wish the Agency to Maintain a Tolerance that the Agency Proposes to Revoke?*

This proposed rule provides a comment period of 60 days for any person to state an interest in retaining a tolerance proposed for revocation. If EPA receives a comment within the 60-day period to that effect, EPA will not proceed to revoke the tolerance immediately. However, EPA will take steps to ensure the submission of any needed

supporting data and will issue an order in the **Federal Register** under the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(f), if needed. The order would specify data needed and the timeframes for its submission, and would require that within 90 days some person or persons notify EPA that they will submit the data. If the data are not submitted as required in the order, EPA will take appropriate action under FFDCA.

EPA issues a final rule after considering comments that are submitted in response to this proposed rule. In addition to submitting comments in response to this proposed rule, you may also submit an objection at the time of the final rule. If you fail to file an objection to the final rule within the time period specified, you will have waived the right to raise any issues resolved in the final rule. After the specified time, issues resolved in the final rule cannot be raised again in any subsequent proceedings.

## **II. Background**

### *A. What Action is the Agency Taking?*

EPA is proposing to revoke the potato tolerance for the fungicide dicloran and the apple, peach, and pear tolerances for the insecticide formetanate hydrochloride.

EPA is proposing the tolerance revocations in follow-up to the Agency's approval (as described in Unit II.A.) of voluntary requests from registrants to amend dicloran and formetanate product labels to delete uses for specific food commodities. Also, in accordance with current Agency practice, EPA is proposing to make minor revisions to the tolerance expression for dicloran and to specific tolerance nomenclatures for dicloran. In addition, in accordance with current Agency practice to describe more clearly the measurement and scope or coverage of the tolerances, including applicable metabolites and degradates, EPA is proposing minor revisions to the tolerance expression for

formetanate hydrochloride. The revisions do not substantively change the tolerance or, in any way, modify the permissible level of residues permitted by the tolerance. It is EPA's general practice to propose revocation of those tolerances for residues of pesticide active ingredients on crop uses for which there are no active registrations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), unless someone submits comments on the proposed rule indicating a need for the tolerance to cover residues in or on imported commodities or legally treated domestic commodities. The following discussion explains the specific changes and the reasons for the changes.

1. *Dicloran*. Because it is no longer Agency practice to distinguish between preharvest and postharvest applications in the tolerance expression, in 40 CFR 180.200, EPA is proposing to remove paragraph (a)(2), redesignate paragraph (a)(1) as paragraph (a), and revise the introductory text containing the tolerance expression in newly designated paragraph (a) by removing the reference concerning preharvest and postharvest applications, to read as set out in the proposed regulatory text at the end of this document.

Also, in the **Federal Register** of December 1, 2010 (75 FR 74714) (FRL-8854-3), EPA published a notice of receipt of requests to voluntarily amend certain dicloran (DCNA) registrations to delete the use for potato, and therefore terminate the last registrations for use of dicloran in or on potato. In the **Federal Register** of November 16, 2011 (76 FR 71022) (FRL-8883-8), EPA approved the cancellation order for amendments to terminate product uses and allowed registrants to sell and distribute existing stocks of the affected products until November 16, 2012. The Agency allowed persons other than the registrant to sell, distribute, or use existing stocks of the affected

products until they are exhausted, provided that it complies with the EPA approved labeling. Recently, the registrant has been in further communication with the Agency, and based on the information provided, EPA believes that existing stocks are likely to be exhausted by December 31, 2014. Therefore, EPA is proposing to revoke the tolerance in newly designated 40 CFR 180.200(a) on potato with an expiration/revocation date of December 31, 2014.

In addition, because it is no longer Agency practice to distinguish between preharvest and postharvest applications in the tolerance definitions, EPA is proposing to revise the commodity terminology in newly designated 40 CFR 180.200(a) from “apricot, postharvest” to “apricot,” “carrot, roots, postharvest” to “carrot, roots,” “cherry, sweet, postharvest,” to “cherry, sweet,” “nectarine, postharvest” to “nectarine,” “peach, postharvest,” to “peach,” “plum, prune, fresh, postharvest” to “plum, prune, fresh,” and “sweet potato, postharvest,” to “sweet potato, roots.”

2. *Formetanate hydrochloride*. In the **Federal Register** of July 13, 2011 (76 FR 41250) (FRL-8879-7), EPA published a notice of receipt of requests to voluntarily amend certain formetanate registrations to delete uses for apple, peach, and pear, and therefore terminate the last registrations for use of formetanate hydrochloride in or on those commodities. In the **Federal Registers** of September 14, 2011 (76 FR 56753) (FRL-8888-2) and November 16, 2011 (76 FR 71021) (FRL-9327-1), EPA approved the cancellation order for amendments to terminate product uses and amended the order to allow registrants to sell and distribute existing stocks of the affected products until January 31, 2012 (which extended the deadline by 60 days beyond that previously allowed in the September 14, 2011 cancellation order). The Agency allowed persons



other than the registrant to sell, distribute, or use existing stocks of the affected products until December 31, 2013. Therefore, EPA is proposing to revoke the tolerances in 40 CFR 180.276(a) on apple; apple, wet pomace; peach; and pear with expiration/revocation dates of December 31, 2013.

In order to describe more clearly the measurement and scope or coverage of the tolerances, EPA is proposing to revise the introductory text containing the tolerance expression in 40 CFR 180.276(a) to read as set out in the proposed regulatory text at the end of this document.

*B. What is the Agency's Authority for Taking this Action?*

A “tolerance” represents the maximum level for residues of pesticide chemicals legally allowed in or on raw agricultural commodities and processed foods. Section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA of 1996, Public Law 104-170, authorizes the establishment of tolerances, exemptions from tolerance requirements, modifications in tolerances, and revocation of tolerances for residues of pesticide chemicals in or on raw agricultural commodities and processed foods. Without a tolerance or exemption, food containing pesticide residues is considered to be unsafe and therefore “adulterated” under FFDCA section 402(a), 21 U.S.C. 342(a). Such food may not be distributed in interstate commerce (21 U.S.C. 331(a)). For a food-use pesticide to be sold and distributed, the pesticide must not only have appropriate tolerances under the FFDCA, but also must be registered under FIFRA (7 U.S.C. 136 *et seq.*). Food-use pesticides not registered in the United States must have tolerances in order for commodities treated with those pesticides to be imported into the United States.

EPA's general practice is to propose revocation of tolerances for residues of pesticide active ingredients on crops for which FIFRA registrations no longer exist and on which the pesticide may therefore no longer be used in the United States. EPA has historically been concerned that retention of tolerances that are not necessary to cover residues in or on legally treated foods may encourage misuse of pesticides within the United States. Nonetheless, EPA will establish and maintain tolerances even when corresponding domestic uses are canceled if the tolerances, which EPA refers to as "import tolerances," are necessary to allow importation into the United States of food containing such pesticide residues. However, where there are no imported commodities that require these import tolerances, the Agency believes it is appropriate to revoke tolerances for unregistered pesticides in order to prevent potential misuse.

Furthermore, as a general matter, the Agency believes that retention of import tolerances not needed to cover any imported food may result in unnecessary restriction on trade of pesticides and foods. Under FFDCA section 408, a tolerance may only be established or maintained if EPA determines that the tolerance is safe based on a number of factors, including an assessment of the aggregate exposure to the pesticide and an assessment of the cumulative effects of such pesticide and other substances that have a common mechanism of toxicity. In doing so, EPA must consider potential contributions to such exposure from all tolerances. If the cumulative risk is such that the tolerances in aggregate are not safe, then every one of these tolerances is potentially vulnerable to revocation. Furthermore, if unneeded tolerances are included in the aggregate and cumulative risk assessments, the estimated exposure to the pesticide would be inflated. Consequently, it may be more difficult for others to obtain needed tolerances or to

register needed new uses. To avoid potential trade restrictions, the Agency is proposing to revoke tolerances for residues on crops for which FIFRA registrations no longer exist, unless someone expresses a need for such tolerances. Through this proposed rule, the Agency is inviting individuals who need these import tolerances to identify themselves and the tolerances that are needed to cover imported commodities.

Parties interested in retention of the tolerances should be aware that additional data may be needed to support retention. These parties should be aware that, under FFDCA section 408(f), if EPA determines that additional information is reasonably required to support the continuation of a tolerance, EPA may require that parties interested in maintaining the tolerances provide the necessary information. If the requisite information is not submitted, EPA may issue an order revoking the tolerance at issue.

### *C. When Do These Actions Become Effective?*

EPA is proposing that the actions proposed in this document will become effective on the date of publication of the final rule in the **Federal Register**. EPA is proposing an expiration/revocation date of December 31, 2014 for revocation of the dicloran tolerance on potato and December 31, 2013 for revocation of the formetanate hydrochloride tolerances on apple; apple, wet pomace; peach; and pear. The Agency believes that these revocation dates allow users to exhaust stocks and allow sufficient time for passage of treated commodities through the channels of trade. However, if EPA is presented with information that existing stocks would still be available and that information is verified, the Agency will consider extending the expiration date of the tolerance. If you have comments regarding existing stocks and whether the effective date

allows sufficient time for treated commodities to clear the channels of trade, please submit comments as described under **SUPPLEMENTARY INFORMATION**.

Any commodities listed in this proposed rule treated with the pesticides subject to this proposed rule, and in the channels of trade following the tolerance revocations, shall be subject to FFDCA section 408(1)(5), as established by FQPA. Under this unit, any residues of these pesticides in or on such food shall not render the food adulterated so long as it is shown to the satisfaction of the Food and Drug Administration that:

1. The residue is present as the result of an application or use of the pesticide at a time and in a manner that was lawful under FIFRA, and
2. The residue does not exceed the level that was authorized at the time of the application or use to be present on the food under a tolerance or exemption from tolerance. Evidence to show that food was lawfully treated may include records that verify the dates when the pesticide was applied to such food.

### **III. International Residue Limits**

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is

different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for formetanate hydrochloride or MRL for dicloran in or on potatoes.

#### **IV. Statutory and Executive Order Reviews**

In this proposed rule, EPA is proposing to revoke specific tolerances established under FFDCA section 408. The Office of Management and Budget (OMB) has exempted this type of action (e.g., tolerance revocation for which extraordinary circumstances do not exist) from review under Executive Order 12866, entitled “*Regulatory Planning and Review*” (58 FR 51735, October 4, 1993). Because this proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed rule is not subject to Executive Order 13211, entitled “*Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*” (66 FR 28355, May 22, 2001). This proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations as required by Executive Order 12898, entitled “*Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*” (59 FR 7629, February 16, 1994); or OMB review or any other Agency action under Executive Order 13045, entitled “*Protection of Children from Environmental Health Risks and Safety Risks*” (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration

of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency previously assessed whether revocations of tolerances might significantly impact a substantial number of small entities and concluded that, as a general matter, these actions do not impose a significant economic impact on a substantial number of small entities. This analysis was published on December 17, 1997 (62 FR 66020) (FRL-5753-1), and was provided to the Chief Counsel for Advocacy of the Small Business Administration. Taking into account this analysis, and available information concerning the pesticides listed in this proposed rule, the Agency hereby certifies that this proposed rule will not have a significant negative economic impact on a substantial number of small entities. In a memorandum dated May 25, 2001, EPA determined that eight conditions must all be satisfied in order for an import tolerance or tolerance exemption revocation to adversely affect a significant number of small entity importers, and that there is a negligible joint probability of all eight conditions holding simultaneously with respect to any particular revocation. This Agency document is available in the docket of this proposed rule. Furthermore, for the pesticides named in this proposed rule, the Agency knows of no extraordinary circumstances that exist as to the present proposed rule that would change the EPA's previous analysis. Any comments about the Agency's determination should be submitted to the EPA along with comments on the proposed rule, and will be addressed prior to issuing a final rule. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution

of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled “*Federalism*” (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This proposed rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this proposed rule does not have any “tribal implications” as described in Executive Order 13175, entitled “*Consultation and Coordination with Indian Tribal Governments*” (65 FR 67249, November 9, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This proposed rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of

power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this proposed rule.

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 19, 2012.

Steve Bradbury,

*Director, Office of Pesticide Programs.*



Therefore, it is proposed that 40 CFR chapter I be amended as follows:

**PART 180—[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Revise § 180.200 to read as follows:

**§ 180.200 Dicloran; tolerances for residues.**

(a) *General.* Tolerances are established for residues of the fungicide dicloran, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only dicloran, 2,6-dichloro-4-nitroaniline, in or on the commodity.

Commodity	Parts per million	Expiration/Revocation Date
Apricot	20	None
Bean, snap, succulent	20	None
Carrot, roots	10	11/2/11
Celery	15	None
Cherry, sweet	20	None
Cucumber	5	None
Endive	10	None
Garlic	5	None
Grape	10	None
Lettuce	10	None
Nectarine	20	None
Onion	10	None
Peach	20	None
Plum, prune, fresh	15	None
Potato	0.25	12/31/14
Rhubarb	10	None
Sweet potato, roots	10	None
Tomato	5	None

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

3. Revise § 180.276 to read as follows:

**§ 180.276 Formetanate hydrochloride; tolerances for residues.**

(a) *General.* Tolerances are established for residues of the insecticide formetanate hydrochloride, including its metabolites and degradates, in or on the commodities in the table in this paragraph. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only formetanate hydrochloride, *N,N*-dimethyl-*N'*-[3-[[[(methylamino)carbonyl]oxy]phenyl]methanimidamide hydrochloride, in or on the commodity.

Commodity	Parts per million	Expiration/Revocation Date
Apple	0.50	12/31/13
Apple, wet pomace	1.5	12/31/13
Grapefruit	1.5	None
Lemon	0.60	None
Lime	0.03	None
Nectarine	0.40	None
Orange	1.5	None
Peach	0.40	12/31/13
Pear	0.50	12/31/13
Tangelo	0.03	None
Tangerine	0.03	None

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]